In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1550V UNPUBLISHED

H.F.,

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 30, 2021

Special Processing Unit (SPU); Findings of Fact; Onset and Site of Vaccination; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Mollie Danielle Gorney, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On October 4, 2019, H.F. filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that he suffered a shoulder injury related to vaccine administration ("SIRVA") after receiving an influenza ("flu") vaccine on October 13, 2016. Petition at 1, ¶¶ 1-3. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the flu vaccine was most likely administered in Petitioner's left deltoid, as alleged, and that onset of Petitioner's pain occurred within 48 hours of vaccination.

I. **Relevant Procedural History**

H.F. filed the Petition in this case, without medical records, shortly before the expiration of the Vaccine Act's statute of limitations.³ Over the subsequent eight-month period, he filed the affidavit and medical records required by the Vaccine Act. Exhibits 1-20, ECF Nos. 6, 11, 15, 19, 22, 25-26. The case was activated and assigned to the SPU on June 5, 2020. ECF No. 29.

During the July 27, 2020 initial status conference, the parties discussed the lack of a notation in the vaccine record indicating the situs of administration. Scheduling Order, issued July 28, 2020, at 1, ECF No. 33. The vaccine record from CVS Pharmacy indicates only that the vaccine was administered intramuscularly in Petitioner's deltoid. Exhibit 1. However, there are multiple entries in the medical records created shortly thereafter indicating Petitioner reported that the flu vaccine was administered in his injured, left deltoid. E.g. Exhibit 2 at 61 (visit one month after vaccination on October 14, 2016). Thus, Petitioner was instructed to forward his demand and supporting documentation and to file a status report regarding his progress accomplishing this task. Scheduling Order at 3, ECF No. 33.

On December 1, 2020, Respondent was ordered to file a status report providing a better estimate of the time needed for the Health & Human Services ("HHS") review and to provide an informal assessment from Respondent's counsel. In the status report, Respondent's counsel noted two potential issues: 1) the lack of documentation regarding the exact site of vaccination and 2) Petitioner's later description of pain which traveled down his arm and of tingling and numbness in his fingers. ECF No. 38. In recent email communications with the parties, Respondent's counsel indicated that she could not state for certain whether a factual ruling regarding the site of vaccination would be needed. See Informal Remark, dated Mar. 15, 2021. She also confirmed the HHS review would, most likely, not occur for at least four more months. *Id.*

When ordered to file his next status report regarding his demand, Petitioner was instructed to file any additional evidence regarding the site of vaccination. Non-pdf

³ Under the Vaccine Act, for a vaccine administered after October 1, 1988, "no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." Section 16(a)(2). Petitioner received the vaccine alleged as causal on October 13, 2016. Exhibit 1. He filed the Petition on October 4, 2019.

Scheduling Order, issued Jan. 29, 2021. In his latest status report, filed on March 15, 2021, Petitioner indicated that he continues to seek further evidence to show the site of vaccination and to finalize his demand. ECF No. 40.

During the parties' email communications, Petitioner's counsel confirmed that it is unlikely further evidence regarding the site of vaccination can be obtained. See Informal Remark, dated Mar. 15, 2021. Thus, I have determined, while awaiting the HHS review, a fact ruling regarding both the site of vaccination and onset of Petitioner's left shoulder pain may help the parties informally resolve this case.

II. Issues

At issue is whether Petitioner received the vaccination alleged as causal in his injured left arm and whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (Table entry for SIRVA following the influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's

failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact

I make the findings after a complete review of the record to include all medical records, affidavits, and additional evidence filed. Specifically, I base the findings on the following evidence:

- The Administration and Consent Form from CVS Pharmacy indicates that the flu vaccine was administered to Petitioner intramuscularly in his deltoid.
 It does not specify whether the site of vaccination was Petitioner's left or right deltoid. Exhibit 1.
- When Petitioner first sought medical care for his left shoulder pain from his primary care provider ("PCP") on November 14, 2016, approximately one month after vaccination, he attributed his pain to the flu vaccine he received in his left arm on October 13, 2016. Exhibit 2 at 61. Reporting immediate pain which worsened over time, he described a constant ache, weakness, swelling, limited range of motion ("ROM"), and difficulty sleeping due to the pain. *Id.* at 61, 65. Petitioner denied any numbness. *Id.* at 65. Petitioner's PCP observed soft tissue and subdeltoid tenderness and limited ROM. *Id.* at 65-66. Elbow, wrist, and hand examinations were normal. *Id.* at 66.
- At a follow-up appointment on January 26, 2017, Petitioner again attributed his left shoulder pain to the flu vaccine he received. Exhibit 2 at 71. He described the vaccination as administered "very high in shoulder." *Id.* For the first five to six weeks, Petitioner experienced left shoulder pain with all

movement. After that, he indicated that he also had "a distracting abnormal sensation traveling down the arm." *Id.*

- In the history he provided before undergoing an EMG on February 6, 2017, Petitioner again attributed his left shoulder pain to the flu vaccine he received in October 2016. Exhibit 16 at 5.
- When seen by his dermatologist for rough spots and eyelid droopiness on February 14, 2017, Petitioner listed "Flu Shot" on his intake form as another concern. Exhibit 19 at 3.
- Petitioner continued to attribute his left shoulder pain to the flu vaccine when seen by an orthopedist on February 17, 2017 (Exhibit 2 at 91) and assessed for physical therapy ("PT") on February 24, 2017 (Exhibit 4 at 6, 12). During his initial PT evaluation, Petitioner reported that the individual administering the flu vaccine "injected it too high and deep," hitting the rotator cuff and bursa. *Id.* at 12.
- When seeking a second orthopedic opinion on August 7, 2017, Petitioner "state[d] he received a flu shot on October 13, 2016 on the lateral aspect of the left shoulder." Exhibit 7 at 13. He described immediate pain which became significant by the next day which was his wife's birthday. In this medical record, it is noted that Petitioner is right-hand dominant. *Id.*
- Throughout the medical records from Petitioner's PCP, lists of his immunizations identify the site of vaccination for flu vaccines he received in 2013, 2014, and 2016 as his left deltoid and in 2017 and 2018 in his right and left buttocks, respectively. Exhibit 2 at 62. It appears Petitioner did not receive a flu vaccine in 2015. Id.

In every post-vaccination record containing a medical history, from the time he first sought treatment on November 14, 2016, Petitioner consistently reported left shoulder pain immediately upon vaccination. Without fail, he attributed his injury to the flu vaccine he received on October 13, 2016, which he described as administered too high and deep. Petitioner also provided extremely consistent accounts of immediate onset, left shoulder pain, and limited ROM during the five to six weeks after vaccination, and additional symptoms of radiating pain, tingling and numbness thereafter. While these entries were based upon information provided by Petitioner, they still should be afforded greater weight than more current representations, as they were uttered contemporaneously with Petitioner's injury for the purposes of obtaining medical care.

The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied <u>to</u> or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when the information is provided by Petitioner.

Additionally, Petitioner's claim of administration in his left deltoid is consistent with where he received prior flu vaccines. Vaccinations Petitioner received in 2013 and 2014 were also administered in his left deltoid. Exhibit 2 at 62. The site of future vaccinations differed, however, suggesting Petitioner may have believed that the vaccine administered in 2016 caused his left shoulder pain. *Id.* Furthermore, it is noted in the medical records that Petitioner is right-handed. Such information provides added support for Petitioner's assertion.

The vaccine record clearly states that Petitioner received the flu vaccine intramuscularly in the deltoid on October 13, 2016. There is nothing in the vaccine record or medical records in this case to indicate administration was in Petitioner's other arm (right) or that the onset of Petitioner's pain was not immediate as Petitioner consistently reported. But I find there is preponderant evidence to establish the vaccination alleged as causal in this case was administered to Petitioner in the left deltoid, and that onset of Petitioner's pain occurred within 48 hours of vaccination.

V. Scheduling Order

Despite my rulings regarding site of vaccination and onset, there are several issues which still exist in this case. Petitioner's SIRVA presentation is not typical, since (starting in December 2016) it included pain which radiated down his arm and numbness and tingling in his fingers. *E.g.* Exhibit 2 at 71. Additionally, Petitioner suffered significant spinal issues in 2014-15. Exhibit 2 at 5-56; Exhibit 21 at 8-48. Petitioner's settlement demand should take into account the foregoing.

Petitioner shall file a status report regarding his demand and supporting documentation by no later than <u>Friday, May 28, 2021</u>. The status report shall indicate the date by which Petitioner provided, or intends to provide, a demand and supporting documentation to Respondent.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master